

HELPER Programme (Substance Misuse) - A phase-specific psychological therapy for people with problematic cannabis use following a first episode of psychosis (ReCAP)

Submission date 23/08/2012	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 23/08/2012	Overall study status Completed	☐ Protocol
Last Edited 11/05/2018	Condition category Mental and Behavioural Disorders	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol

Background and study aims

Schizophrenia and related psychoses often make it harder for sufferers to concentrate, remember things like appointments, change the way they think about things when they need to (flexibility) and do several things at the same time. This might also make it harder for people to take part in talking therapies like Cognitive-behavioural therapy (CBT). The researchers running this study hope to use Cognitive Remediation (CR) to help people get more out of CBT. CR is a way of training the brain to deal with difficulty in concentration, memory and so on, based on practicing puzzles and other tasks. Other studies have shown it can work to improve these things but have not used it before CBT. This study will investigate whether the use of a course of Cognitive Remediation (CR) prior to participation in CBT will improve the effectiveness of the CBT. CR is a form of brain-training using a programme of mental puzzles and other tasks which is known to be effective in improving cognitive capacities.

Who can participate?

Patients aged between 16-35 with a mental health disorder that take cannabis.

What does the study involve?

Participants are randomly allocated to one of two groups. Those in group 1 are given 40 hours of CR over a 12 week period before CBT. Those in group 2 are given 40 hours of social support over a 12 week period before CBT. All participants are given CBT for a period of between 12 and 30 weeks. Each participant is assessed at the start of the study using a wide range of measures including the severity of their symptoms and their cognitive capacities (how well they think). They are assessed again after they have completed CR or social support and every 6 weeks for another 30 weeks after they start their CBT.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?
Lancashire Care NHS Trust (UK)

When is the study starting and how long is it expected to run for?
January 2009 to April 2011

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Ms Louise Worrell
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
4756

Study information

Scientific Title
HELPER Programme (Substance Misuse) - A phase-specific psychological therapy for people with problematic cannabis use following a first episode of psychosis (ReCAP)

Acronym
HELPER (ReCAP)

Study objectives
We are conducting an exploratory trial to evaluate whether a psychological therapy following a first episode of psychosis is effective at reducing cannabis use when compared to usual care.

This study will also investigate whether a brief intervention (4.5 months) is as effective as a longer one (9 months). This is a randomised controlled trial with 3 treatment groups, long-term treatment, short-term treatment, and treatment as usual.

Ethics approval required

Old ethics approval format

Ethics approval(s)

08/H1015/82

Primary study design

Interventional

Study design

Randomised interventional trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Psychosis

Interventions

64 patients waiting for CBT after their first episode of schizophrenia, who agree to take part, will be randomly selected either for CR or support from a Support Time and Recovery Worker. They will see either the therapist for 40 hrs or the support worker for the same amount of time over 3 months. After this both group will have CBT as part of normal NHS service, for 12 - 30 sessions. Participant's symptoms and neuropsychological skills will be assessed at recruitment and after 12 weeks by an assessor is blind to which group they are in. They will then have delusions and hallucinations reassessed for every 6 weeks for another 30 weeks, during CBT.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Cannabis

Key secondary outcome(s)

No secondary outcome measures

Completion date

20/04/2011

Eligibility**Key inclusion criteria**

1. Meeting DSMIV criteria for schizophrenia, schizophreniform disorder, schizoaffective disorder, delusional disorder, or psychosis not otherwise specified using a checklist of criteria and review of case notes; and confirmation of this diagnosis using the structured clinical interview for DSMIV Axis 1 disorders
2. DSMIV diagnosis of cannabis dependence or abuse using the appropriate sections of the structured clinical interview
3. A history of cannabis use of at least 1 day per week in at least half the weeks in the 3mths prior to assessment (those who are misusing other illicit substances or alcohol will not be excluded)
4. Aged 16-35
5. No significant history of organic factors implicated in the aetiology of psychotic symptoms
6. Male & female participants

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. No stable accommodation (i.e. street homeless or roofless)
2. Does not possess sufficient English to reliably complete assessments
3. Not able to give informed consent

Date of first enrolment

05/01/2009

Date of final enrolment

20/04/2011

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Lancashire Care NHS Trust

Preston

United Kingdom

PR5 6AW

Sponsor information

Organisation

Lancashire Care NHS Trust (UK)

ROR

<https://ror.org/03zefc030>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2014		Yes	No

Results article	results	01/03/2015	Yes	No
Interim results article	interim results	01/04/2015	Yes	No